#### PATENT APPLICATION

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE.

In re application of

Docket No: Q80109

Toru YANO, et al.

Appln. No.: 10/787,415

Group Art Unit: 1796

Examiner: Alicia TOSCANO

Confirmation No.: 4540
Filed: February 27, 2004

For: BIODEGRADABLE RESIN COMPOSITION AND BIODEGRADABLE RESIN

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### DECLARATION UNDER 37 C.F.R. § 1.132

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

I, Toru YANO, do declare and state:

In March of 1986, I graduated from the Graduate School of Okayama University of Science, receiving a Doctor's degree in the field of Material Science,

In January of 1992, I was employed by Nishikawa Rubber Co., Ltd. and assigned to the Automotive Division of the R&D Department of said company.

From October of 1994 to the present, I have principally been engaged in research relating to polymerization of biodegradable resins.

I am a co-inventor of the invention described and claimed in my above-identified application,

My invention relates to a biodegradable resin composition comprising an L-lactic acid unit-containing resin (1) and a D-lactic acid unit-containing resin (2). The L-lactic acid unit-

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containing resin (1) is a homopolymer of L-lactic acid, and the D-lactic acid unit-containing resin (2) is a copolymer of D-lactic acid and a saccharide. Moreover, resin (2) is present in an amount of from 3 to 5 parts by weight per 100 parts by weight of resin (1).

I am familiar with the prosecution of the above-identified application, and the most recent Office Action dated December 7, 2007.

In order to demonstrate that it is the combination of resin (1) which is L-lactic acid (homopolymer) and resin (2) which is D-lactic acid copolymer with saccharide which provides the effects of the invention, as opposed to blending with a saccharide alone or blending with D-lactic acid (homopolymer) alone, I report below on experimentation which was conducted by myself or under my direct supervision. The test data presented herein also establishes criticality in the claimed range of from 3 to 5 parts by weight of resin (2) per 100 parts by weight of resin (1) for achieving the effects of my invention.

Specifically, the procedures illustrated at pages 15-28 of my specification were supplemented to include additional samples pursuant to the Examiner's suggestion as set forth at page 3 of the Office Action dated December 7, 2007, as follows:

- 1-(a): 100 parts L-lactic acid homopolymer, blended with 1 part saccharide
- 1-(b): 100 parts L-lactic acid homopolymer, blended with 1 part D-lactic acid homopolymer
- 1-(c): 100 parts L-lactic acid homopolymer, blended with 1 part D-lactic-co-saccharide
  The composition of the above Sample No. 1-(c) corresponds to Sample No. 14 in Table 4'
  of the second Declaration under 37 C.F.R. § 1.132 dated November 16, 2007.
- (2) Samples requested in page 4 of Office Action:
  - 2-(a): 100 parts L-lactic acid homopolymer
  - 2-(b): 100 parts D-lactic-co-saccharide

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2-(c): 100 parts D-lactic acid homopolymer

- 2-(d): 100 parts L-lactic acid homopolymer, blended with 25 parts D-lactic acid homopolymer
- 2-(e): 100 parts L-lactic acid homopolymer, blended with 30 parts D-lactic acid homopolymer
- 2-(f): 100 parts L-lactic acid homopolymer, blended with 25 parts D-lactic-cosaccharide
- 2-(g): 100 parts L-lactic acid homopolymer, blended with 30 parts D-lactic-cosaccharide

The compositions of the above Samples Nos. 2-(f) and 2-(g) correspond to Sample Nos. 18 and 19 in Table 4', respectively.

## (3) Additional Samples:

- 100 parts L-lactic acid homopolymer, blended with 3 parts D-lactic acid homopolymer
- 100 parts L-lactic acid homopolymer, blended with 5 parts D-lactic acid homopolymer
- 100 parts L-lactic acid homopolymer, blended with 11 parts D-lactic acid homopolymer

Add. Ex.: 100 parts L-lactic acid homopolymer, blended with 3 parts saccharide

The samples thus prepared were evaluated with respect to Tensile strength (MPa),

Elongation (%), Melting point (°C) and Crystallization rate, the results of which are set forth in the Table shown below. Maximum Tensile strength and Elongation at break were evaluated as described at page 24 of the specification.

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	2-(a)	2-(b)	2-(c)	1-(c)	15	16	17	2-(f)	2-(q)	1-(a)	Add B
Resin (1)	100		-	100	100	100	100	100	100	100	100
Resin (2)		100		1	3	5	16501 · 26	25	30		
Resin (3)			100				1 .				-
Starch				-						1	3
Tensile strength (MPa)	-		-	53	53	48	3743525	7.4 TA	8.1		
Elongation (%)	•		•	4.2	4.1	3.5	P. 72.1500		0.6		
Metting point (*C)	184.9	134,4	127.4	185.2	185.7	186.2	190	200 ≤	200 ≤	183.7	186
Crystallization rate	Small	Small	Small	Small	Medium	Large	Large	Lame	Lame	Small	Small

	1-(b)	18	19	20	2-(d)	2-(0)
Resin (1)	100	100	100	100	100	100
Rosin (2)	-			-		
Resin (3)	1	3	5	11	25	30
Tensile strength (MPa)	57	34	-35	15	6.4	4.5
Elongstion (%)	4.9	2.5	2.7	1	0.4	0.3
Meting point (C) 202.22.	184.3	185,1	183.9	190	200 ≤	200 ≤
Crystallization rate	Small	Small	Small"	Large :	Large"	Large

I comment on the significance of the test data as follows,

- (a) If the amount of resin (2) is 1 part by weight, the composition results in a small crystallization rate (Sample No. 1-(a)).
- (b) If the amount of resin (2) exceeds 5 parts by weight, the material cost is increased and also the tensile strength and elongation are lowered (Sample Nos. 17, 2-(f) and 2(g)).
- (c) The stereocomplex of L-lactic acid and D-lactic acid is known. However, the formulation of L-lactic acid and D-lactic-co-saccharide is novel. With the addition of 3 to 5 parts by weight of the copolymer, a crystallization rate suitable for productivity was achieved. In the case of formulation of L-lactic acid with D-lactic acid, the crystallization rate is small, and further, the tensile strength and the elongation are deteriorated.

# Significance of the Difference in Crystallization Rate:

Sample Nos. 15 and 16 according to the invention have a crystallization rate of 
"medium" or higher. To the contrary, Sample Nos. 18 and 19 representing ordinary 
stereocomplex materials have a crystallization rate of "small." A crystallization rate of

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"medium" or higher enables an increase in the molding cycle speed, which leads to cost reduction.

Significant Differences in Tensile Strength and Elongation Represent an Advance in the Art:

Resin materials generally used for automobiles are ABS and PP. Tensile test data (i.e., tensile strength and elongation measured in the same manner) for ABS and PP are additionally given below.

	General-ourpose	automobile material		
	ABS[*1]	PP(-2)		
Tensile Strength (MPa)	44	134		
Elongation (%)	16	10		

- \*1: ABS used is A330 available from Techno Polymer Co., Ltd.
- \*2: PP used is Nobrene BZH-51 available from Sumitomo Chemical Co., Ltd.

Comparing the results, it can be seen that Sample Nos. 15 and 16 according to my invention exhibit a higher tensile strength than that of ABS which is of itself required to have a high tensile strength among materials for automobile parts. To the contrary, Sample Nos. 18 and 19 have a tensile strength as low as that of PP. Accordingly, although conventional polylactic acid materials have been applicable only to the extent of PP, the present invention extends applicability, in terms of tensile strength, up to that provided by ABS. This is a surprising and unexpected effect of the invention.

As to criticality in the claimed range of 3 to 5 parts by weight of resin (2) per 100 parts by weight of resin (1), the test data presented in this third Declaration shows that only the samples in the invention, i.e., Sample Nos. 15 and 16, provided both high tensile strength and clongation in addition to a medium or large crystallization rate. Sample No. 1-(c) containing

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resin (2) in an amount of 1 part by weight per 100 parts by weight of resin (1) provided only a small crystallization rate and therefore lower productivity. On the other hand, in Sample Nos. 17, 2-(f) and 2-(g) where resin (2) was present in amounts exceeding 5 parts by weight per 100 parts by weight of resin (1), the crystallization rate (productivity) was large, but the resulting resin compositions suffered from reduced tensile strength and elongation.

Sample Nos. 2-(a), 2-(b) and 2-(c) consisting of resin (1), resin (2) or resin (3) alone did not provide the effects of the invention (small crystallization rate). Also, Sample No. 1-(a) and Add. Ex. consisting of 100 parts by weight of resin (1) and 1 or 3 parts by weight of starch, also did not provide the effects of the invention (small crystallization rate).

Sample Nos. 1-(b), 18 and 19, having a composition containing resin (3) in amounts of 1, 3 or 5 parts by weight per 100 parts by weight of resin (1), respectively, did not provide the effects of the invention (small crystallization rate). Resin (3) is a homopolymer of D-lactic acid. Sample Nos. 20, 2-(d) and 2-(e) having a composition of 11, 25 or 30 parts of resin (3) per 100 parts by weight of resin (1), respectively, exhibited a large crystallization rate but suffered in terms of low tensile strength and elongation. Likewise, these samples also did not achieve the effects of the invention.

The above-noted results demonstrate that it is the combination of L-lactic acid (homopolymer) and D-lactic acid copolymer with saccharide which provides the effects of the invention, as opposed to blending with a saccharide alone or blending with D-lactic acid (homopolymer) alone. The above-noted results also establish criticality in the claimed resin composition containing resin (2) in an amount of from 3 to 5 parts by weight per 100 parts by weight of resin (1), which results could not have been expected from the cited prior art.

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I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 2008, 08,0/

Joru Yano